Limitations of these studies include failure to control for important confounders, small sample size and short study period, which may have impact on the risk of cancer. **CONCLUSIONS:** Given the fact that cancers are rare and often take a long time to develop, further studies require very large population with long follow up time to have sufficient power to detect a possible effect. This, combined with small proportion of insulin users who were exposed to glargine, may be a reason to studies that found no association, which leaves a question of a class effect. Future studies to explore the effect of all other insulins and the possible mechanism may help to untangle this question.

PCN5

ASSESSMENT OF NEUROPATHY IN CLAIMS DATA AND THE ASSOCIATION WITH DOCETAXEL (DC) AND PACLITAXEL (PC) IN ADJUVANT BREAST CANCER (BC)

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OBJECTIVES: Neuropathy, a common side effect of taxanes, is often dose-limiting and may result in changes in treatment. This study examined the occurrence of neuropathy in claims data from commercially insured US patients with BC treated with adjuvant DC or PC. **METHODS:** This retrospective database analysis used eligibility, medical and pharmacy claims data from a large US health care organization, including subjects with a claim for BC and a claim for DC or PC-containing chemotherapy from 1/1/98–12/31/05. Subjects were stratified by dosing interval (weekly (qw) or Q 21 days (q3w)). Neuropathy was defined using ICD-9-CM codes 356.4, 356.8, 356.9, 357.2, 357.4, 357.5, 357.6, 357.7, 357.8x, 357.9, 377.34, 354.4, 354.5, 354.8, 354.9, 355.7x, 355.8 and 355.9. Neuropathy grade could not be assessed by claims data. Subjects were followed until the earliest of date of death or last enrollment or 12/31/06. Chi-square was used to compare descriptive variables. Logistic regression (LR) was used to examine the independent association of index medication and neuropathy. Covariates included age, geographic region, baseline co-morbidity score and use of medications for neuropathy. **RESULTS:** A total of 3619 subjects were identified for PC (n = 329, qw; 1685, q3w) or DC (n = 204, qw; 1045, q3w). A significantly lower frequency of neuropathy was seen in the follow-up period for DC-based treatments compared to PC (7.0% vs 10.6%, $p < 0.001$). Differences were also noted when stratifying by dosing interval (6.7% vs 10.0%; $p = 0.003$ in q3w, 9.3% vs 13.7%; $p = 0.061$ in qw). After adjusting for covariates, the odds of neuropathy remained significantly lower with DC-based treatment (OR = 0.70, CI = 0.559, 0.920; $p = 0.010$). **CONCLUSIONS:** Less neuropathy was noted with DC-based treatment compared to PC. This difference persisted with stratification by dosing interval. The lower occurrence of neuropathy with DC may favor maintenance of dose intensity.

PCN6

EVALUATION OF THE RELIABILITY OF ELECTRONIC MEDICAL RECORD DATA IN IDENTIFYING COMORBID CONDITIONS AMONG PATIENTS WITH ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC)

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OBJECTIVES: Traditional methods for identifying comorbidities in retrospective observational research have relied primarily on claims data. The purpose of this study was to validate a 2-phased strategy to search EMR data to identify comorbidities among cancer patients. **METHODS:** Advanced stage NSCLC patients (N = 2513) who received chemotherapy from July 1, 2006–June 30, 2008 were identified using iKnowMed, US Oncology's proprietary oncology-specific EMR system. EMR data were searched for documentation of the following comorbidities: moderate/severe renal disease, congestive heart failure (CHF), dementia, chronic obstructive pulmonary disease (COPD), cerebrovascular disease, paralysis, diabetes, peripheral vascular disease (PVD), myocardial infarction (MI), liver disease, and AIDS. The search was conducted in 2 phases. Initially, a series of programmatic queries were conducted to search standardized information on concomitant illnesses, patient history, review of systems, and diagnoses other than cancer. In a second phase, keyword searches of text-based fields (i.e., physician dictation notes, problem lists, etc.) were conducted. To evaluate the validity of the comorbidity information derived from the EMR, we randomly sampled 450 patients for whom we found no documentation of comorbidities using our 2-phased approach. We then exhaustively scanned available claims data and conducted comprehensive chart reviews to confirm that these patients did not have any of the comorbidities of interest. Negative predictive values (true negatives / (true negatives + false negatives) were calculated. **RESULTS:** Using our 2-phased search of the EMR, we found an overall prevalence of comorbidities of 22%. The most commonly identified conditions were COPD, diabetes, PVD, and CHF. Among the random sample of 450 patients for whom no comorbidities were identified, we identified 36 who had evidence of comorbidities after scanning claims data and conducting chart reviews (negative predictive value = 0.92). **CONCLUSIONS:** Results of this study suggest that efficient queries of EMR data may provide reliable data on comorbid conditions among cancer patients.

PCN7

A COMPARISON OF INTRAVENOUS AND ORAL FORMULATIONS OF FLUDARABINE IN THE TREATMENT OF CHRONIC LYMPHOCYTIC LEUKEMIA

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OBJECTIVES: Fludarabine (F) has been proven to be highly effective in the treatment of chronic lymphocytic leukemia (CLL). Both oral and IV F are used internationally. Recently, the oral formulation of fludarabine was approved in the US for treating CLL, which may offer advantages for providers, payers and patients. This study is a systematic review of clinical trial and retrospective data for oral and IV fludarabine, focusing on differences in efficacy, complications, resource utilization, cost and patient preference. **METHODS:** PubMed and manual bibliographic searches were conducted to identify relevant publications for oral and IV F. Studies were included if they were: 1) published after January 1, 2000, 2) derived from human subjects, 3) written or translated in English 4) focused on CLL, and 5) evaluated efficacy, resource utilization, complications, costs or patient preference. **RESULTS:** There were 17 articles that met inclusion criteria. Results indicated that the pharmacokinetic profile of oral and IV F were similar, with 25 mg/m^2 of IV being equivalent to 40 mg/m^2 of oral. Oral F has similar efficacy and safety to IV F, and eliminates infusion related adverse events and administration costs. Studies indicated that providing oral F was more convenient for patients and nurses due to the absence of IV administration. No cost or pharmacoeconomic data were found. **CONCLUSIONS:** Oral and IV F were found to have similar clinical efficacy and safety. The oral formulation may potentially lead to substantial economic benefits when factoring in possible reductions in infusion related administration and adverse events. Future studies need to compare real-world clinical outcomes and economic impact of oral vs. IV F, taking into account decision-making in clinical practice of both health care providers and patients.

PCN8

IMPACT OF 5-HT3-RECEPTOR ANTAGONIST STEP THERAPY ON CHEMOTHERAPY INDUCED NAUSEA AND VOMITING ASSOCIATED HOSPITAL AND EMERGENCY ROOM EVENTS

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OBJECTIVES: To explore the impact of step therapy policies requiring the use of a 1st-generation 5-hydroxytryptamine- receptor antagonist (5-HT$_3$-RA) treatment before palonosetron (a 2nd generation 5-HT$_3$-RA) on the incremental risk of chemotherapy induced nausea and vomiting (CINV) associated with a hospital or emergency room (ER) event. **METHODS:** Claims data (PharMetrics) were used to identify continuously enrolled adult patients diagnosed with breast cancer (BC) and initiated on cyclophosphamide-based chemotherapy (CT) within 4 months post-diagnosis or with lung cancer (LC) and initiated on carboplatin-based CT. Patients were stratified into those initiated and maintained on palonosetron throughout CT (Group 1) versus those treated on day 1/cycle 1 with any other 5-HT$_3$-RA regimen (Group 2). Risks and frequency for CINV-associated hospital or ER events identified through ICD-9-CM codes for nausea, vomiting, and/or dehydration during a 6-month follow-up period were estimated using logistic and Poisson regression models, controlling for age, gender (LC only), comorbidity, and CT days. **RESULTS:** Of 3606 BC and 4497 LC identified patients, 1864 BC (52%) and 1806 LC (40%) initiated palonosetron. Groups 1 and 2 had comparable comorbidity and CT treatment days. Compared to group 2 patients, group 1 patients had a significantly lower probability of CINV-associated hospital or ER events (3.5% vs. 5.5% in BC and 9.5% vs. 12.8% in LC), had 47.4% (BC) and 29.1% (LC) fewer hospital or ER days with CINV, and fewer 5-HT$_3$-RA claims (mean ± SD 6.2 ± 3.3 vs. 7.9 ± 4.1 in BC and 7.7 ± 4.9 vs. 10.3 ± 6.4 in LC), all at $p < 0.05$. Risk for CINV was 38% (BC) and 29% (LC) lower for group 1 patients (Odds Ratio = 0.62 in BC and 0.71 in LC, $p < 0.05$). **CONCLUSIONS:** LC or BC patients initiated and maintained on palonosetron throughout CT were at significantly lower risk for costly CINV versus those on any other 5-HT$_3$-RA on day 1/cycle 1 of CT treatment.

PCN9

USING PROPENSITY SCORES TO REDUCE SELECTION BIAS IN AN OBSERVATIONAL STUDY COMPARING RASBURICASE TO ALLOPURINOL IN THE US

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BACKGROUND Randomized clinical trials remain the gold standard in evaluating different drug therapies on outcomes but are resource intensive. Retrospective studies using observational data are inexpensive but prone to selection bias due to non-random differences between the intervention and comparator groups. The Propensity Score (PS) method is a novel, multivariate adjustment procedure that reduces confounding and selection bias. **METHODS:** This case-control study used the *Health Facts*® database (Cerner Corporation, Kansas City, MO), which integrates patient information from hospitals throughout the United States. Cancer patients receiving rasburicase or allopurinol were eligible for study inclusion. Both drugs reduce uric acid (UA) elevation otherwise resulting from tumor lysis syndrome. The PS is the